Welcome to Antisense News

In this edition we will cover recent significant developments within our industry in relation to the validation of our technology and relevant commercial deals in our space. We also highlight key information relating to the status of our development projects. In addition, already this year we have been very busy promoting the ANP story through a variety of investment forums including conferences, presentations and roadshows which have all led to increasing interest in our Company and new broker research and coverage both locally and overseas.

At Antisense Therapeutics we strive extremely hard to add value to our projects by advancing their development. When developing drugs for large global markets, it is important to consider the licensing transactions and drug approvals that take place in our field which give us confidence in the commercial attractiveness of our projects and that validate our technology.

In addition to the value creation in our projects and the desire to address significant medical needs with those drugs, we also work very hard in building the investment profile and wider interest in our story. We are proactive with all our communications and in keeping our shareholders fully informed as to the happenings within our Company and the commercial landscape that we operate in. The central focus of our Board and Management is to build substantial value in the Company so that our shareholders will be able to realise significant appreciation in the value of their shareholdings.

Mark Diamond
MD and CEO

Commercial transactions, deals and technology validation

ATL1103

As you would be aware, our lead drug in development, ATL1103, is currently undergoing testing in a Phase II clinical trial in patients with the growth disorder, acromegaly.

In February this year, Roche acquired the rights to an oral acromegaly drug, Octreolin™ in Phase III development in a deal worth US$595 million (US$65 million upfront and milestone payments up to US$530 million).

We believe that this transaction provides an important guide on the potential value of ATL1103 which, subject to successful outcomes from the current Phase II trial, would be positioned to move into Phase III studies.

The Roche drug is an oral version of an existing first line treatment of acromegaly (octreotide) that is currently only available as an injectable drug so it is expected to take market share away from those drugs. Clinical studies have confirmed that octreotide-like drugs are only effective in treating approximately 60% of patients with acromegaly. We believe ATL1103 may have broader activity than the octreotide-like drugs and on this basis we would not expect it to compete with this new oral drug, but ATL1103 would be positioned for the high percentage of patients where octreotide is ineffective and where there are currently limited treatment options.
Commercial transactions, deals and technology validation (continued)

**ATL1103 (continued)**

A number of research analysts commented favourably about the Roche acromegaly deal.

**RBS Morgans** noted the following: Roche (RHHBY) has tied up the worldwide rights to Chiasma’s Phase III drug for acromegaly, a rare and progressive disease caused by the over-production of growth hormone. The pharma giant paid $65 million upfront and promised up to $530 million more in milestones in order to nail down marketing rights to the oral drug. Genetech will take over U.S. marketing if the FDA approves the treatment. Our comment “could have positive implications for Antisense Therapeutics.” (Source: FiercePharma/RBS Morgans).

Independent investment research house, **Bioshares** in noting the Roche deal also stated, “This deal confirms the interest in this area (acromegaly) from larger pharmaceutical companies.”

In their research note entitled “Platform validated and current clinical trials funded” **Patersons Securities** added in reference to the Roche deal, “If the Phase III study is positive (completion expected in 2Q 2013), Roche would be positioned to take this oral drug up against Novartis’ injected drug, Sandostatin-LAR, the current standard of care. In an interview with Globes last year, Chiasma indicated that the acromegaly market as a whole is worth about US$500m with potential to expand its size with approval for neuroendocrine tumors, which is worth about US$600m. This news is significant in that it signals the entry of a new major pharmaceutical company into the acromegaly market and provides a guide on the future value of ATL1103, which ANP expects to have broader therapeutic activity than this oral version.”

**ATL1102**

In further commercial transaction news relevant to our space and more specifically to **ATL1102** for multiple sclerosis (MS), in February last year Biogen Idec gained all the rights to MS drug Tysabri® from Elan. With sales of US$1.6 billion per annum, Biogen Idec paid US$3.25 billion plus payments on future sales.

This is relevant to ANP as Tysabri® has the same biological target (VLA-4) as ATL1102 which suggests that ATL1102 could be as effective as Tysabri® in treating patients with MS. Subject to the successful completion of the current toxicology study, ATL1102 could move into Phase IIb studies in 2014.

In research published by **Patersons Securities** in March 2013, they stated “ATL1102’s biological target is validated by Biogen Idec’s drug Tysabri, a monoclonal antibody drug to VLA-4. Whilst regarded as one of the most effective drugs in the treatment of MS, Tysabri causes a lethal side effect in some patients... it also has the disadvantage of being intravenously administered which requires patients to be hospitalized for their treatment. ANP sees ATL1102 profiling as potentially equipotent to Tysabri but safer and with the convenience advantage of self-administration (in a pre-filled syringe like insulin).”

**ATL1101**

In December 2009 OncoGenex licensed a 2nd generation antisense compound (custirsen) for prostate cancer to Teva after positive Phase II trial results in a deal worth US$430 million. This drug has subsequently moved into Phase III clinical trials, results of which are due before the end of the year.

This is relevant to ANP because it shows pharma interest in clinical stage antisense drugs for prostate cancer. It also provides a key technology validation event with the upcoming custirsen Phase III study results. If successful, this will be the first antisense drug to show long term survival benefits in cancer patients and, accordingly ANP anticipates this could materially increase partnering and investor interest in, and in turn the value of, ATL1101 for cancer.
FDA approval of Kynamro™

In January this year ANP’s technology partner Isis Pharmaceuticals Inc. received U.S. FDA approval with respect to its drug Kynamro™. Kynamro™ will now be marketed in the U.S. by Isis’s marketing partner, Genzyme for the treatment of a rare genetic disease characterized by extreme cholesterol levels.

This was an important event for antisense technology as it is the first systemically administered (into the body’s blood system) antisense drug to reach the market. For ANP, it provides excellent validation for the compounds we are developing as Kynamro™ is an antisense drug with the same second generation antisense platform chemistry as ATL1103, ATL1102 and ATL1101.

In Nature Medicine, one of the world’s leading science publications, they noted the significance of this approval in an article entitled ‘Biotech comes to its ‘antisenses’ after hard-won drug approval’ where they state that with the recent approval of Kynamro™ “antisense technology seems finally ready to make an impact.” The CEO of Isis, Dr Stanley Crooke, is quoted as saying “We feel this is a critical step in the final validation of the technology.”

Bioshares said that the approval of Kynamro™ was “positive news for antisense drug developers.”

EP Vantage, a leading online pharmaceutical comment and analysis service said “The approval in the U.S. of Isis Pharmaceutical’s Kynamro™ has finally validated antisense technology as a therapeutic approach. And for Isis’s long-term collaborator, Antisense Therapeutics, the approval is more than just affirmation of the technologies potential; it provides concrete advantages in the shape of clinical development pathway and a precedent that could help it hook partners and investors.”

Project Pipeline Development Status

ATL1103 Phase II trial underway

ANP recently announced that the ATL1103 Phase II trial in acromegaly patients is underway with the key results of the drug’s effect on blood IGF-I levels anticipated by the end of 2013.

In the previously conducted Phase I trial, ATL1103 was shown to be safe and exhibiting a preliminary effect in reducing IGF-I levels, which is the key objective for the treatment of the growth disorder acromegaly. This Phase I trial was conducted in normal volunteers and we anticipate a greater reduction in IGF-I levels in the Phase II trial as it is being conducted in acromegaly patients who have elevated Growth Hormone and IGF-I levels, and longer and higher dosing regimens are being investigated.

If ATL1103 shows the desired level of effect in reducing IGF-I in this Phase II study while continuing to demonstrate its safe profile, the drug would then be in a position to progress into Phase III trials.

ANP is developing ATL1103 amidst a favourable commercial backdrop as evidenced by the Roche deal mentioned earlier and the acknowledged need for better and more cost effective drugs to treat acromegaly.

ANP’s Chief Investigator for the current ATL1103 Phase II trial is Dr. Peter Trainer, one of the world’s leading authorities in the field of acromegaly. Dr. Trainer was involved in the clinical trials of a number of existing drugs to treat acromegaly, including the drug Somavert® which has the same biological target as ATL1103 (the Growth Hormone receptor) and sales of approximately US$200 million per annum. ANP expects ATL1103 to be less expensive than the Somavert® treatment and to have an improved safety profile and a more convenient dosing regimen.
**Project Pipeline Development Status** (continued)

**ATL1102 to commence toxicology study and stem cell mobilization investigation**

ANP has announced that it will conduct a toxicology study to support a potential future Phase IIb trial in MS patients. We have been able to significantly lower the costs of this study with a more streamlined study design and by being able to use existing ATL1102 drug product. So for less than $300,000 we expect to complete the toxicology study by the end of 2013. With successful results, ATL1102 could move into late stage (Phase IIb) clinical trials in MS patients.

ANP had previously advanced the drug as far as Phase Ila with ATL1102 proving safe and effective in reducing MS lesions in MS patients.

ANP recently announced the granting of a new US patent on ATL1102 for the treatment of MS taking its patent life to 2029 and potentially extendible to 2034.

In a new additional application of ATL1102, ANP's development partner in ATL1102, Tianjin International Joint Academy of Biotechnology and Medicine (TJAB) is to conduct a stem cell mobilization study of ATL1102 in primates at their facilities in Tianjin in China and at their cost. This study will investigate the effectiveness of ATL1102 in stimulating the early release of immune stem cells which are used in the treatment of cancer where immune cells are otherwise destroyed by the toxic effects of chemotherapy. Following this study the next step is to investigate ATL1102's efficacy at releasing stem cells in a human trial. In parallel with the conduct of the study in primates, ANP and TJAB are proposing to make an application to conduct this human trial in China.

**ATL1101 is positioned to move into clinical development**

Having already assembled a robust pre-clinical pharmacology data package on ATL1101, the drug is now positioned to move into clinical development for certain forms of cancer including prostate cancer. Whilst potentially looking to secure a development partner for this project, as highlighted earlier we believe that interest in and the commercial value of ATL1101 may increase markedly if OncoGenex achieves favourable Phase III trial results (which are expected before the end of the year) for their antisense prostate cancer drug.

**Conferences, presentations and roadshows**

So far this year we have been pro-active in reaching out to the global investment market. In addition to regular domestic roadshows, investor and analyst presentations, we have been invited to speak at two important and significant conferences in the United States and our Chief Investigator on the ATL1103 project spoke at a major scientific conference on acromegaly.

21st to 23rd March, 2013, 9th Consensus Conference on “Medical Treatment of Acromegaly”, Amsterdam
- Dr Peter Trainer, Chief Investigator for ANP’s ATL1103 Phase II study presentation on the project and previously generated Phase I trial results.

17th to 20th March, 2013, ROTH Capital Partners 25th Annual Growth Stock Conference, United States
- CEO and MD Mark Diamond invited to present a Company overview.

11th February, 2013, BIO CEO and Investor Conference, United States
- CEO and MD Mark Diamond presents on advancements in ANP’s product pipeline including the current Phase II trial of ATL1103 as well as significant progress being made in relation to the antisense technology platform.

February, 2013
- Follow on roadshows to investment managers and analysts in New York, Boston and London.
Recent Research coverage


RBS Morgans: 22nd February 2013, Daily Healthcare News; Coverage of Roche acromegaly deal.

Nature Medicine: March 2013 article “Biotech comes to its antisenses after hard won drug approval.”

EP Vantage: Interview with CEO, Mark Diamond. 22nd February 2013, “Antisense aims to ride Kynamro’s slipstream to market.”

Funding

Last year we embarked on a number of funding initiatives that have positioned the Company with cash reserves forecast to fund our planned development activities well into 2014. As at the half year ended December 2012, ANP had cash reserves of $5.1 million.

Parting Message from the CEO

2013 is shaping as a watershed year for antisense as a technology and ANP as a Company. I am particularly excited that by the end of this year, we may have our acromegaly drug ATL1103 ready to move into Phase III trials, the final stage of drug development. In addition to this, we could have ATL1102 potentially positioned for long term clinical trials in MS patients following its current toxicology study. This would establish us as having one of the most advanced product pipelines in Australian biotech.

We expect that the activities ongoing at Isis (our technology collaboration partner) and their Big Pharma partners will ensure that a steady stream of news will flow on the scientific and commercial progress of the antisense technology that should continue to increase both market and pharmaceutical partnering interest in antisense drug programs. The value in our drug assets is not only underlined by this unique peer validation but also by recent significant commercial transactions in the disease areas where our drugs are focussed, and where our drugs profile as potentially superior to those that are available today for treating those diseases.

Drug development is a long journey and does at times test the patience of its supporters, however we are approaching very significant near term value inflection points and accordingly, I’m hopeful this will result in a significant re-rating of ANP that I trust will reward our long term and loyal shareholders. I take this opportunity to thank you for your support and I look forward to reporting on our progress towards this goal.